

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' JOINT SURREPLY IN FURTHER OPPOSITION TO DEFENDANT BAYER CORPORATION'S INDIVIDUAL MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

In other, similar AWP cases, including *Suffolk*,¹ this Court previously sustained all fraud-based AWP and Best Price claims against Bayer, except those released by the 2001 and 2003 Bayer settlements.² Furthermore, this Court ruled that the 2001 and 2003 Bayer settlements resolved only the specified claims as to the specified drugs for the specified release period stated in the settlements. *Id.* Plaintiffs concede the release of the specified claims for Kogenate, Gamimune, Cipro and Adalat (“settlement drugs”) that are covered by the scope of the settlements.

However, Bayer now argues for the first time in its reply memorandum (“Bayer Reply”) that all claims for the settlement drugs outside of their respective settlements, which have not been released, should also be dismissed.³ Bayer further contends that by conceding the release of their claims covered by the settlements, plaintiffs lack the specificity to proceed as to any other drugs or any other time periods.

In support, Bayer contends that with regard to Kogenate and Gamimune plaintiffs fail to allege: (i) a single purchase or false AWP for the pre-settlement period; (ii) that Bayer misreported best price or underpaid rebates during any period (also for Cipro and Adalat at any time); and that (iii) these drugs were “physician administered” drugs (“PADS”) that were reimbursed at actual cost not AWP or if reimbursed at AWP, Bayer provided New York Medicaid actual ASP information that should have alerted to the falsehood of the AWPs Bayer caused to be reported. Lastly, Bayer contends plaintiffs do not explain how they calculated “market prices” or spreads for Bayer’s other drugs and have no good faith basis to describe the AWPs as fraudulent.

¹For clarity and consistency, plaintiffs use the same definitions of all terms and cases cited in their corresponding individual opposition memorandum (“Bayer Opp.”). Additionally, all other causes not addressed herein are addressed in Plaintiffs Consolidated Sur-Reply to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as “Consolidated Sur-Reply”).

²See *Suffolk II*, 2004 WL 2387125 at *3; *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 321 F. Supp. 2d 187 at 207 (D. Mass. 2004) sustaining Montana’s AWP and Best Price claims ..

³These arguments should be stricken since they are first raised in the reply. *North Am. Specialty Ins. Co. v. Laalme*, 258 F.3d 35, 45 (1st Cir. 2001); *M & D Cycles, Inc. v. Am. Honda Motor Co.*, 208 F.Supp.2d 115, 122 (D.N.H. 2002) (refusing to consider contractual provision first asserted in reply brief as basis for summary judgment).

As illustrated in great detail in their opposition to the Bayer MTD (“MTD Opp”), plaintiffs plead facts in support of their Best Price and fraudulent AWP claims with sufficient specificity to meet the requirements of Fed. R. Civ. P. 9(b) as well as this Court’s prior rulings in *Suffolk*.⁴ See Bayer Opp at 3-5. Plaintiffs’ showing stands and is not disturbed in the least by the sea of red herrings in Bayer’s Reply, to wit:

First, the settlements speak for themselves and the scope defined therein.

Second, Bayer acknowledges the scope of the settlements. For Gamimune and Kogenate Bayer states, “the scope of 2001 Settlement resolved allegations “that Bayer improperly inflated the AWP’s of the drugs ... **from January 1993 through August 1999.**” Bayer MTD at 2 (emphasis added). Furthermore, in its Proposed Order Bayer does not seek the dismissal of AWP or Best Price claims for Gamimune and Kogenate after the “effective date of the 2001 settlement”.⁵ Nor does Bayer seek the dismissal of best price claims for Cipro or Adalat outside of the 2003 settlement period. See Bayer Proposed Order ¶¶2-4. Bayer effectively conceded these claims.

Third, amazingly, Bayer contends that after conceding the release of claims by the 2001 and 2003 settlements, plaintiffs “now” claim that they have viable claims outside of the settlement periods. The argument makes no sense. Plaintiffs’ complaints clearly seek to recover Medicaid overpayments for all Bayer products “**from 1992 to the present** as a result of defendants’ fraudulent and misleading schemes that overcharge the New York State Medicaid plaintiffs Program [] for prescription drugs bought” by plaintiffs.⁶ (Emphasis added). Plaintiffs’ acknowledgement of the settlements’ releases merely narrows the scope of their original claims; it

⁴ All other causes are addressed in Plaintiffs Consolidated Sur-Reply to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as “Consolidated MTD Sur-Reply”).

⁵ Plaintiffs in no way accept the language of the Proposed Order. Bayer does not withdraw or change any language of its Proposed Order in the Bayer Reply.

⁶ CC ¶1; NSAC ¶1; see ¶¶ 307, 326-27; CC Exh. A; NSAC ¶¶ 288, 304-306; NSAC Exh. B.

does not expand them or give birth to new ones. .

Fourth, plaintiffs allege (1) the name of every Bayer drug at issue in their case, and (2) false AWP and fraudulent spreads in support of all their AWP and Best Price claims, including those covered by the 2001 and 2003 settlements. *See* CC Exh. A & B; NSAC Exh. A & B.

Fifth, neither settlement altered Bayer's duty to report, or to cause to be reported, an accurate AWP. Moreover, to the extent Bayer's actual ASP differed from the published AWP this further illustrates the falsity of Bayer's published AWP and WACs. Finally, the mere fact that Bayer is now providing ASP in no way guarantees that such ASP is accurate, nor does it absolve Bayer of any future liability.

Sixth, the phrase "physician administered" has no operative or controlling significance in terms of reimbursement under New York Medicaid or whether such reimbursement is based on AWP. The Statute provides that New York Medicaid reimburses "for drugs provided by medical practitioners and claimed separately by the practitioners, [at] the actual cost of the drugs to the practitioners." N.Y. Soc. Serv. Law §367-a(9) (emphasis added). Thus, in order for a physician administered (or any other) drug to be reimbursed at "actual cost", the "medical practitioner" must: (i) provide the drug; and, (ii) claim reimbursement separately. *See id.* There are many specialty pharmacies, hospitals, home health services and other non-practitioners in New York who seek reimbursement of PADs from Medicaid at AWP. Whether and how a drug is reimbursed by Medicare Part B is utterly irrelevant to Medicaid. (i.e., Medicare Part B covered drugs are reimbursed based on J-Codes, not NDCs).

Seventh, Bayer's PAD argument is disingenuous, as it was an independent pharmacy whistler-blower that resulted in the 2001 Settlement- not a practitioner. Moreover, Kogenate and Gamimune can be self-administered or administered by a home health aide or another trained individual. *See* http://www.aetna.com/formulary/inject_2006.html.

CONCLUSION

For the reasons set forth herein and in Plaintiffs' Opposition Memorandum, only claims against Bayer covered by the 2001 Settlement Agreement and 2003 Settlement Agreement for the time period discussed in plaintiffs' Bayer opposition should be dismissed, the remainder of Bayer's Motion to Dismiss should be denied.

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Respectfully submitted,

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